

Please cancel Claim 16.

Please amend Claim 17 as follows:

- 94 17. (Amended) A kit according to Claim 15 wherein n is an integer averaging from about 13 to about 15.

Please add new Claim 21 as follows:

21. A method according to Claim 1 wherein the beverage composition comprises from about 0.001% to about 0.5% of the compound, by weight of the composition.

95 [ Please add new Claim 22 as follows: ]

22. A kit according to Claim 11 wherein the beverage composition comprises from about 0.001% to about 0.5% of the compound, by weight of the composition.

#### REMARKS

Applicant thanks the Examiner for the consideration given the present application. Upon entry of the amendments and claim additions herein, Claims 1 – 22 will be pending.

Claim 1 has been amended to recite use of beverage compositions which are substantially free of calcium and fluoride. Claim 11 has been amended to correct an inadvertent error in form. Claim 11 has also been amended to recite beverage compositions which are substantially free of calcium and fluoride. Support for these amendments is set forth in the present specification at page 6, line 28 through page 7, line 12. No new matter is introduced through these amendments.

Claims 2 and 12 have been amended to depend upon newly added Claims 21 and 22, respectively. Claims 21 and 22 have been added; these new claims recite methods and kits, wherein the composition utilized comprises from about 0.001% to about 0.5% of the polyphosphate compound. Support for these new claims is set forth in the originally filed specification at page 6, lines 8 – 11. No new matter is added through the introduction of these claims.

Claims 6 and 16 have been canceled. As a result, Claims 7 and 17 have been amended for dependency.

The Examiner has rejected the claims based on 35 U.S.C. §§ 112, 102(b), and 103(a). Applicant addresses each of these rejections, as set forth below:

#### The Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected Claims 1 – 20 based on 35 U.S.C. § 112, second paragraph. The Examiner states that the claims do not recite the concentrations or percent levels of the enabled

phosphate or polyphosphate sodium or potassium salts providing treatment against dental erosion, in the absence of calcium and fluoride salts.

Applicant respectfully traverses this rejection. Applicant has fully enabled unrecited levels of the polyphosphate compound. Applicant states in his specification that certain levels are *preferred*, although not requisite for enablement. For example, at the specification at page 6, lines 8 – 11, Applicant states that: “Preferably, the present beverage compositions comprise from about 0.001% to about 0.5%, more preferably from about 0.03% to about 0.3%, even more preferably from about 0.05% to about 0.2%, and most preferably from about 0.05% to about 0.1% of the compound, by weight of the composition.” Applicant asserts that nothing in this statement of *preferences* in any way indicates that such preferences are required for enablement of the present invention.

Similarly, Applicant has fully enabled beverage compositions that may either contain, or be substantially free of, calcium and / or fluoride. To exemplify, in the specification at page 6, lines 28 – 31, Applicant states: “It has been further excitingly discovered that treatment of dental erosion is provided herein through use of the beverage composition even wherein the beverage composition is substantially free of components which are often associated with treatment of dental erosion, *i.e.*, fluoride and / or calcium.” Thus, Applicant has made clear that the present methods and kits are useful against dental erosion with or even without calcium and / or fluoride. Thus, although often preferable, the absence of calcium and / or fluoride is not required to enable the present invention. However, in an effort to advance prosecution of the present Application for reasons other than the present 35 U.S.C. § 112 rejection, Applicant notes that Claims 1 and 11 have been amended such that the beverage composition utilized is substantially free of calcium and fluoride. Support for these amendments is set forth in the present specification at page 6, line 28 through page 7, line 12. No new matter is introduced through these amendments.

*The Rejections Under 35 U.S.C. §§ 102(b) and 103(a)*

The Examiner has rejected Claims 1 – 20 based on 35 U.S.C. §§ 102(b) and 103(a) over each of Muhler, ZA 6904743, published 1972 (referred to as “Muhler”) and McDonald *et al.*, “Laboratory Studies Concerning the Effect of Acid-Containing Beverages on Enamel Dissolution and Experimental Dental Caries”, *J. Dent. Res.*, pp. 211 – 216, published 1973 (referred to as “McDonald *et al.*”). The Examiner has further rejected Claims 1 – 20 based on 35 U.S.C. § 103(a) over Muhler or McDonald *et al.*, in combination with any of the U.S. Patents cited on Examiner’s Form PTO-892. The Examiner has also rejected Claims 1, 2, 11, and 12 based on 35 U.S.C. §§ 102(b) and 103(a) over each of Gilmor, “The Effect on Dental Caries-Activity of Supplementing Diets with Phosphates: A Review”, *J. Public Health Dentistry*, Vol. 29, No. 3, pp. 188 – 207 (1969) and Ruessner *et al.*, “Effects of Phosphates in Acid-Containing Beverages on Tooth Erosion”, *J. Dent. Res.*, Vol. 54, No.

2, pp. 365 – 370 (1975). Applicant traverses each of these rejections, in view of the remarks and amendments herein.

Applicant first traverses the rejection of Claims 1 – 20 based on Muhler. The Examiner states that Muhler anticipates the addition of sodium or potassium phosphate salts to a low pH beverage to reduce its tooth eroding potential. The Examiner further states that the selection of species of sodium or potassium polyphosphates would thereby be immediately envisioned in view of Muhler, citing *In re Schaumann*, 197 USPQ 5 (CCPA 1978). Respectfully, Applicant traverses this rejection.

Muhler and McDonald *et al.* disclose only the use of monosodium dihydrogen phosphate (“MDP”,  $\text{NaH}_2\text{PO}_4$ ) for use in treating dental erosion. MDP is a simple, non-polymeric, ionic phosphate form which is unrelated, and does not encompass, the polyphosphate compounds utilized in the present invention. Accordingly, neither Muhler nor McDonald *et al.* discloses, or even suggests, the use of the present polyphosphate compounds for treatment against dental erosion.

The Examiner cites *In Re Schaumann* to support this anticipation position, stating that use of the present polyphosphate compounds would be immediately envisioned, and thus anticipated, based on the decision of *Schaumann* and either the Muhler or McDonald *et al.* references. Respectfully, the Examiner’s dependence on *Schaumann* is misplaced and flawed. In *Schaumann*, the CCPA held that a genus can anticipate a claim to a species given the right set of circumstances. Applicant asserts that *Schaumann* has no applicability to the present case (under any set of circumstances), given that the polyphosphate compounds, which have a specific chemical structure as set forth in the claims, cannot in any way be classified as a species of MDP. Accordingly, there can be no anticipation of Claims 1 – 20 (and now, as amended, Claims 1 – 22) based on Muhler or McDonald *et al.* because there is no specific, general, or even implicit disclosure of the use of the present polyphosphate compounds against dental erosion.

Additionally, Claims 1 – 20 (and now, as amended, Claims 1 – 22) would have been non-obvious of either of Muhler and McDonald *et al.* for several reasons. As stated above, Muhler and McDonald *et al.* each disclose the use of MDP (again, monosodium dihydrogen phosphate ( $\text{NaH}_2\text{PO}_4$ )) for treatment of dental erosion. These references fail to explicitly or implicitly disclose or even suggest the use of the defined polyphosphate compounds recited in Applicant’s pending claims. One of ordinary skill would not have been led to substitute the presently recited polyphosphate compounds for the MDP – there is certainly no disclosure in Muhler or McDonald *et al.* to suggest this substitution. Indeed, the presently recited polyphosphate compounds and MDP bear little resemblance structurally, as the former is a polymer and the latter is a free ionic species.

Applicant also respectfully traverses the rejection of Claims 11 – 20 in view of Muhler or McDonald *et al.* based on *In re Haller*, 73 USPQ 403 (CCPA 1947). The Examiner has cited *Haller* for the premise that “novelty cannot be predicated on printed instructions.”

However, Applicant traverses this rejection, as well as the Examiner’s reliance on *Haller*. Indeed, in the more contemporary cases *In re Miller*, 164 USPQ 46 (CCPA 1969) and *In re Gulack*, 217 USPQ 401 (Fed. Cir. 1983), which were both subsequent to *Haller*, articles comprising previously known compositions, in association with information which was functionally related to such composition, were held novel and non-obvious over the known compositions. For example, in *Miller*, which related to printed information on a measuring device, the Court stated:

[The Examiner’s] characterization of printed matter as “unpatentable” is beside the point; no attempt is here being made to patent printed matter as such. The fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination. Here there is a new and unobvious functional relationship between a measuring receptacle, volumetric indicia thereon . . . and a legend indicating the ratio, and in our judgment the appealed claims properly define this relationship.

See Miller, at third paragraph from conclusion of opinion.

The Federal Circuit affirmed this holding in *Gulack*, even while recognizing that the “sole difference” between the claimed article and the prior art composition was the printed material. In *Gulack*, the Federal Circuit stated:

A functional relationship of the precise type found by the CCPA in *Miller* – to size or to type of substrate, or conveying information about [the] substrate – is not required. What is required is the existence of differences between the appealed claims and the prior art sufficient to establish patentability.

See Gulack, Section II, B.

Taken in the context of the present invention, Claims 11 – 20 (and also, as added herein, Claim 22) are indeed patentable over the disclosures of Muhler or McDonald *et al.* The information referred to in independent Claim 11, *i.e.*, information that use of the beverage composition provides treatment against dental erosion, is clearly functionally related to the beverage composition itself. It is representative of the present discovery that the polyphosphate compounds recited in the claims are surprisingly effective against dental erosion. Moreover, the kits of Claims 11 – 20 and 22 are directive, such that a consumer will understand the benefits of the present discovery and have the ability to capitalize on such benefits. Thus, the utility of the present compositions is furthered

because the consumer will understand the benefits, and be encouraged to utilize, the beverage composition based on this surprising and previously unknown use.

Additionally, similar to the reasons stated above with respect to non-obviousness, Applicant asserts that the kits of Claims 11 – 20 (and now also 22) would have been non-obvious over the cited references. For the reasons stated above, it would have been non-obvious to one of ordinary skill that the defined polyphosphate compositions were useful against dental erosion. Accordingly, kits comprising the information in association with the beverage compositions would have also been non-obvious over the cited references.

The Examiner has further combined each of Muhler and McDonald *et al.* with any of the various patents cited by the Examiner on Form PTO-892. Applicant asserts that the Examiner is using impermissible hindsight to allege that the present polyphosphate compounds could obviously be substituted to MDP to provide the dental benefit claimed herein. Furthermore, Applicant respectfully asserts that the Examiner has failed to provide any concrete basis for characterizing these two types of compounds as interchangeable for the purpose of treating dental erosion. Applicant asserts that, collectively, these patents disclose the polyphosphate compound utilized in the present claims, but fail to disclose or even suggest any use against dental erosion. Moreover, these references fail to suggest that the present polyphosphate compounds would be useful as a substitute for MDP (again, monosodium dihydrogen phosphate ( $\text{NaH}_2\text{PO}_4$ )) for the purpose of fighting dental erosion.

Accordingly, for all of the reasons stated above, Applicant respectfully asserts that Claims 1 – 20 and new Claims 21 and 22 are indeed novel, non-obvious, and thus patentable over each of Muhler and McDonald *et al.*, alone or each in combination with the U.S. Patents cited by the Examiner on Form PTO-892.

Finally, the Examiner has rejected Claims 1, 2, 11, and 12 based on 35 U.S.C. §§ 102(b) and 103(a) over Gilmore or, in the alternative, Ruessner *et al.* The Examiner states that each of these claims do not exclude both fluoride and calcium, which were studied by the investigators for their protective dental benefit. In an effort to advance prosecution of the present case, Applicant has amended independent Claims 1 and 11 to recite compositions that are substantially free of calcium and fluoride, as defined in the specification. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of these claims, since the claims now incorporate the limitations of now canceled Claims 6 and 16, respectively.

#### Election of Species

Pursuant to 35 U.S.C. § 121, the Examiner has required Applicant to elect a single disclosed species of each of the following categories:

- (a) a polyphosphate salt of the Claim 1 formula;
- (b) A species of beverage selected from fruit juice, carbonated or non-carbonated tea, milk, or another species;
- (c) A species of sweetener; and
- (d) Free of one or both of calcium and fluoride.

Applicant hereby provisionally elects, with traverse, the following:

- (a) sodium hexametaphosphate, wherein n is 21;
- (b) beverages containing fruit juice;
- (c) carbohydrate sweeteners; and
- (d) substantially free of calcium and fluoride, as defined in the specification.

Applicants respectfully traverse the examiner's request for an election of species in the present application. MPEP § 803 sets forth the following two criteria for a proper restriction requirement between patentably distinct inventions: (1) The inventions must be independent or distinct as claimed; and (2) There must be a serious burden on the examiner if restriction is not required.

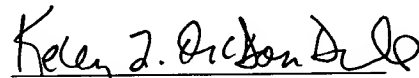
The Examiner has failed to satisfy criteria (2) in requiring the present election. Because the present invention is tailored to methods and kits that utilize the defined polyphosphate compounds described in the application, a serious searching burden is not required of the Examiner.

In view of the foregoing, the Examiner has failed to submit a proper election of species requirement. Accordingly, it is respectfully requested that the Examiner reconsider and withdraw the requirement.

#### CONCLUSION

For all of the above reasons, and in view of the amendments herein, it is respectfully requested that the Examiner withdraw the rejections under 35 U.S.C. §§ 102(b), 103(a), and 112 and allow Claims 1 – 22 as pending herein. If the Examiner believes that personal contact would be advantageous to the disposition of this case, he is respectfully requested to contact the undersigned at his earliest convenience.

Respectfully submitted,



Kelly L. McDow-Dunham  
Attorney for Applicant  
Registration No. 43,787

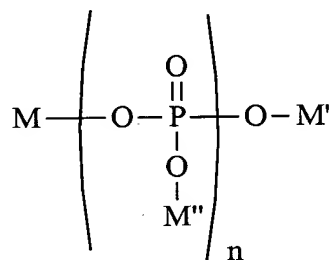
April 23, 2001  
Cincinnati, Ohio  
Tel: 513-634-0102

Version with Markings to Show Changes Made

In the Claims:

Claim 1 has been amended as follows:

1. (Amended) A method of treating dental erosion comprising orally administering to a mammal a beverage composition having a pH of less than about 5;  
wherein the beverage composition comprises a compound having the structure:



wherein n is an integer averaging from about 7 to about 100 and M, M', and M'' are each, independently, selected from the group consisting of sodium and potassium, and wherein the beverage composition is substantially free of calcium and fluoride.

Claim 2 has been amended as follows:

2. (Amended) A method according to Claim ~~1~~21 wherein the beverage composition has a pH from about 2 to about 4.5.

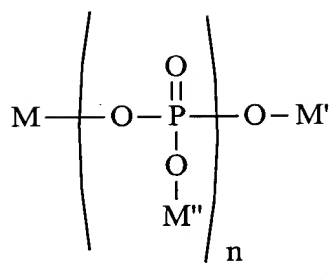
Claim 6 has been canceled.

Claim 7 has been amended as follows:

7. (Amended) A method according to Claim ~~6~~5 wherein n is an integer averaging from about 13 to about 25.

Claim 11 has been amended as follows:

11. (Amended) A kit comprising:
  - (e) a beverage composition having a pH of less than about 5; wherein the beverage composition comprises a compound having the structure:



wherein n is an integer averaging from about 7 to about 100 and M, M', and M'' are each, independently, selected from the group consisting of sodium and potassium, and wherein the beverage composition is substantially free of calcium and fluoride according to Claim 1; and

- (b) information that use of the beverage composition provides treatment against dental erosion.

Claim 12 has been amended as follows:

12. (Amended) A kit according to Claim 11-22 wherein the beverage composition has a pH from about 2 to about 4.5.

Claim 16 has been canceled.

Claim 17 has been amended as follows:

17. (Amended) A kit according to Claim 14-15 wherein n is an integer averaging from about 13 to about 25.

Claim 21 has been added as follows:

21. A method according to Claim 1 wherein the beverage composition comprises from about 0.001% to about 0.5% of the compound, by weight of the composition.

Claim 22 has been added as follows:

22. A kit according to Claim 11 wherein the beverage composition comprises from about 0.001% to about 0.5% of the compound, by weight of the composition.